

(19)

Europäisches Patentamt

European Patent Office

Office européen des brevets



(11)

EP 0 706 356 B1

(12)

## EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention  
of the grant of the patent:  
05.03.1997 Bulletin 1997/10

(51) Int. Cl.<sup>6</sup>: A61F 5/453  
// A61M25/02

(21) Application number: 94920415.0

(86) International application number:  
PCT/DK94/00268

(22) Date of filing: 29.06.1994

(87) International publication number:  
WO 95/01144 (12.01.1995 Gazette 1995/03)

## (54) EXTERNAL URINARY CATHETER

EXTERNER HARNKATHETER

CATHETER URINAIRE EXTERIEUR

(84) Designated Contracting States:  
AT BE CH DE DK ES FR GB GR IE IT LI LU MC NL  
PT SE

(30) Priority: 02.07.1993 DK 793/93

(43) Date of publication of application:  
17.04.1996 Bulletin 1996/16

(73) Proprietor: COLOPLAST A/S  
DK-2980 Kokkedal (DK)

(72) Inventor: TANGHÖJ, Allan  
DK-2000 Frederiksberg C (DK)

(74) Representative: Raffnsøe, Knud Rosenstand  
Internationalt Patent-Bureau,  
23 Høje Taastrup Boulevard  
2630 Taastrup (DK)

(56) References cited:  
DE-A- 520 401 GB-A- 2 126 483  
US-A- 4 388 923

EP 0 706 356 B1

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

form stability that its outer shape is preserved at the place where it is fastened by the foreskin.

In relation to the prior art catheter according to above GB patent application there is thereby obtained a substantially less disturbing position without the risk of tissue damage as a result of that only the extreme portion of glans is covered by the inner catheter member.

Thereby, the possibility is further obtained that the catheter according to the invention may be manufactured as a "one-size" product, which considerably reduces the cost of storage and thus makes the production less expensive.

The improved form stability in the area at the transition to the discharge spout entails that the catheter member through a suitable outer shape may be produced with an improved security against falling off in use due to a pull or compressive load.

The invention will now be explained in detail with reference to the schematical drawings, in which

Fig. 1 shows a sectional view of a preferred embodiment of the catheter according to the invention, Fig. 2 the catheter shown in Fig. 1 in an applied condition, and Figs. 3 to 7 show differently modified designs.

The example shown in Figs. 1 and 2 of an external urinary catheter according to the invention comprises an inner catheter member 1 and a tubular discharge spout 2 intended for connection of the catheter with a hose, not shown, leading to a urine collection bag that may be of a known design.

The catheter member 1 and the discharge spout 2 are manufactured in one piece, e.g. by injection moulding of thermoplastic elastomeric material.

The catheter member 1, which as shown in Fig. 2 in the state of use is intended to be placed under the foreskin 3 in contact with the head or glans 4 of penis, has in the embodiment shown a short axial extent of 5 to 35 mm, that in use it only covers the extreme portion of glans outside the point where glans has its largest diameter.

It is thereby prevented, that the catheter member 1 in the state of use is placed with its end edge 5 against the sensitive skin band between glans and foreskin.

At the transition to the discharge spout 2 the in itself elastically resilient catheter element 1 may, as shown, be designed with such a form stability that in use it preserves its outer shape at the place where the catheter member is fastened by the extreme portion of the foreskin 3.

In the embodiment in Figs. 1 and 2 the increased form stability at the transition between the catheter member 1 and the discharge spout 2 is obtained in a simple manner in that the catheter member 1 is designed with an increased wall thickness in this local area.

The illustrated catheter member 1 is thus designed with an almost bowl-shaped profile, where a substan-

tially plane outer surface 6 is provided about the discharge spout 2 substantially perpendicular to the discharge spout 2, whereas the side wall of the bowl-shaped profile is formed by a skirt portion 7, which joins the outer surface 6 via a shoulder-like ledge 8.

The internal side of the catheter member 1 constitutes an arched bowl-shaped bottom face 9 fitting to the shape of the extreme portion of glans 4.

The application is effected in that the catheter member 1 with the foreskin 3 retracted is placed against glans 4, the discharge spout being placed opposite the mouth of urethra, after which the foreskin 3 is passed out and around the catheter member 1 and fastens this in that the slightly stretched elastic foreskin presses against the outer surface 6.

According to the invention there is used an outer holder member 10 to obtain an additionally secure fastening of the catheter member, said holder member being manufactured as a separate member with a tubular part 11 enveloping the discharge spout 2 but can be displaced axially thereon, possibly in connection with a backstop in the discharge spout 2, thereby diminishing the outer diameter thereof.

In connection with the spout-shaped part 11 the holder member 10 in the embodiment in Figs. 1 and 2 has a substantially bowl-shaped profile 12 having a substantially uniform wall thickness.

The holder member 10 may like the catheter member 1 be manufactured by injection moulding of a thermoplastic elastomer.

Upon application, after that the catheter member 1 has been placed against glans 4 in the above described manner the holder member 10 is pressed against the outside of the foreskin 3 after this has been passed up around the catheter member 1.

The design of the holder member 10 as a separate member that may be displaced on the discharge spout 2 entails the advantage that in case of a tensile load on the discharge spout 2, e.g. due to the weight of the urine collection bag in use only a pull in the catheter member will be exerted, since the tensile load causes an elastic extension and thus a somewhat smaller diameter of the discharge spout 2, whereas the holder member 10 is less affected. The tensile load will thus entail an increased squeeze effect on the extreme portion of the foreskin 3.

The fastening principle may thus in a way be said to be load compensating.

Figs. 3 to 7 show various alternative designs.

In Fig. 3 the catheter member 13 and the holder member 14 are both formed with a bowl-shaped cross-section having a substantially uniform wall thickness. The enhanced form stability at the transition between the catheter member 13 and the discharge spout 15 is here obtained in that the catheter member 13 is provided with one or more circumferential ribs 16 on the outer side.

In the embodiment in Fig. 4, in which the catheter member 17 and the holder member 18 have almost the

lung festzuhalten, dadurch gekennzeichnet, dass das innere Katheterelement (1) eine kurze axiale Länge von 5-35 mm aufweist, um in dieser Lage den äussersten Teil der Eichel (Glans) (4) an der Stelle, wo diese ihren grössten Durchmesser aufweist, zu decken, und dass das äussere Halteelement (10, 14, 18, 23, 25, 28) ein ringförmiges Ausgussteil (11) zur axial verschiebbaren Anordnung um die Ausgusstülle (2) des inneren Katheterelements umfasst, um ein axiales Verschieben des Halteelements in eine Gebrauchsstellung zu ermöglichen, in welcher ein an das ringförmige Ausgussteil (11) integriert angeschlossener Teil des Halteelements zumindest in einen Teil der dem darunterliegenden inneren Katheterelement gegenüberliegenden Aussenseite der Vorhaut eingreift.

2. Externer Urinkatheter nach Anspruch 1, dadurch gekennzeichnet, dass das innere Katheterelement im Bereich des Übergangs zu der Ausgusstülle (2) mit Absteifungsmitteln versehen ist, um dessen Aussenseite Formstabilität zu verleihen.
3. Externer Urinkatheter nach Anspruch 2, dadurch gekennzeichnet, dass das innere Katheterelement (1) um die Ausgusstülle (2) herum eine im wesentlichen ebene, zur Ausgusstülle im wesentlichen senkrecht verlaufende Anlagefläche (6) aufweist, die an einen kurzen Schürzenabschnitt (7) über einen schulterähnlichen Absatz (8) anschliesst.
4. Externer Urinkatheter nach Anspruch 1, 2 oder 3, dadurch gekennzeichnet, dass der in die Aussenseite der Vorhaut eingreifende Teil des äusseren Halteelements (10, 14, 28) im wesentlichen schalenförmig ist.
5. Externer Urinkatheter nach Anspruch 3, dadurch gekennzeichnet, dass das äussere Halteelement (23, 26) mit einer an die Aussenseite des inneren Katheterelements (20, 24) angepassten Innenfläche ausgebildet ist.
6. Externer Urinkatheter nach Anspruch 3, dadurch gekennzeichnet, dass das äussere Halteelement (25) um die Ausgusstülle herum als ein Kragenteil mit einer im wesentlichen ebenen Unterseite (26) ausgeformt ist.
7. Externer Urinkatheter nach Anspruch 1, 2 oder 3, dadurch gekennzeichnet, dass das Katheterelement (17) an seiner proximalen Endkante mit einer nach innen verlaufenden, verhältnismässig weichen Dichtungslippe (19) versehen ist.
8. Externer Urinkatheter nach Anspruch 2, dadurch gekennzeichnet, dass das Katheterelement (13) auf der Aussenseite mit einer zirkular verlaufenden

Rippe (16) versehen ist.

9. Externer Urinkatheter nach Anspruch 2, dass das Katheterelement (27) im wesentlichen schalenförmig und mit einem eingebetteten, zirkularen Absteifring (30) versehen ist.

#### Revendications

1. Cathéter urinaire extérieur pour le soulagement à l'incontinence d'urine des hommes comprenant un élément (1, 13, 17, 20, 24, 27) intérieur de cathéter avec une goulotte (2) tubulaire de décharge à être reliée à un tuyau, ledit élément de cathéter pouvant être arrangé, en usage, dans une position sous le prépuce (3) d'un pénis en contact de surface avec la tête (le gland) (4) du pénis, et un élément (10) séparé et extérieur de maintien pour le contact circconférentiel avec le côté extérieur du prépuce afin de maintenir l'élément (1) intérieur du cathéter dans ladite position caractérisé en ce que l'élément (1) intérieur de cathéter présente une longueur axiale courte de 5 à 35 mm de telle manière à couvrir dans ladite position la partie extrême du gland (4) en dehors du point où le gland présente son diamètre le plus large, l'élément (10, 14, 18, 23, 25, 28) extérieur de maintien comprenant une portion (11) tubulaire de goulotte à être arrangée de manière à pouvoir se déplacer axialement autour de la goulotte (2) de décharge de l'élément intérieur de cathéter pour permettre l'élément de maintien de se déplacer axialement vers une position d'usage dans laquelle une partie de l'élément de maintien intégralement reliée à la portion (11) tubulaire de goulotte est en contact avec au moins une partie de côté extérieur du prépuce opposé à l'élément intérieur de cathéter sous-jacent.
2. Cathéter urinaire extérieur selon la revendication 1, caractérisé en ce que l'élément intérieur de cathéter dans l'endroit à la transition vers la goulotte (2) de décharge est formé avec des moyens de renforcement afin de pourvoir une stabilité de forme à son côté extérieur.
3. Cathéter urinaire extérieur selon la revendication 2, caractérisé en ce que l'élément (1) intérieur de cathéter autour de la goulotte (2) de décharge présente une face (6) d'appui essentiellement plane et essentiellement perpendiculaire à la goulotte de décharge, ladite face d'appui joignant une portion (7) courte de jupe via une saillie (8) semblable à une épaule.
4. Cathéter urinaire extérieur selon la revendication 1, 2 ou 3 caractérisé en ce que la partie de l'élément (10, 14, 28) extérieur de maintien en contact avec le côté extérieure du prépuce est essentiellement en forme de coupe.

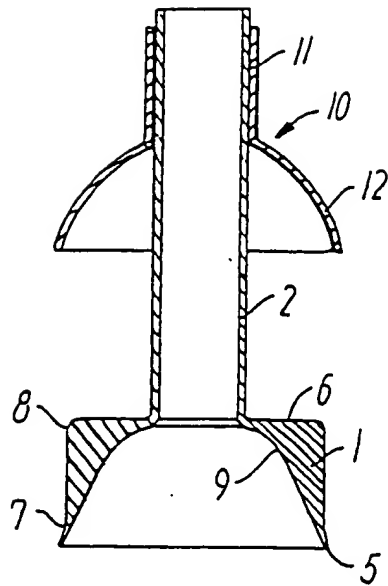


FIG. 1

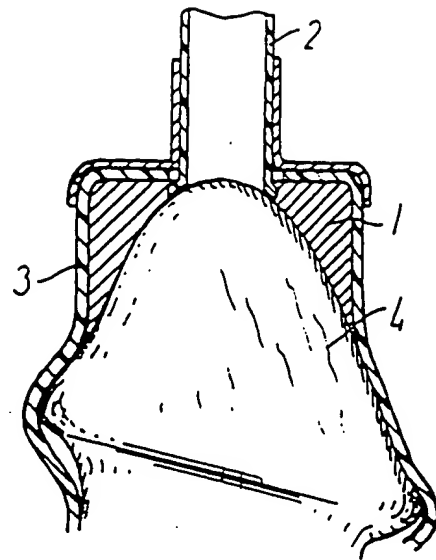


FIG. 2

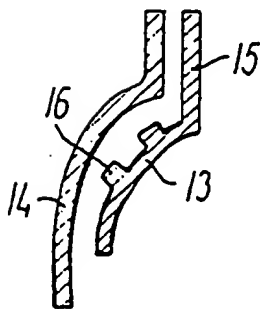


FIG. 3

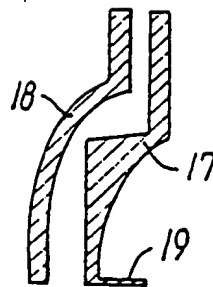


FIG. 4

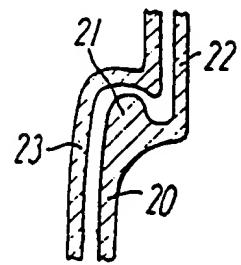


FIG. 5

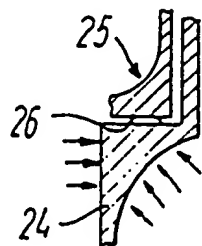


FIG. 6

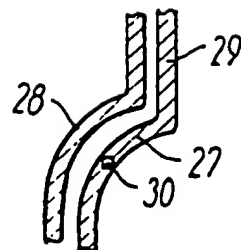


FIG. 7